

REMARKS

In the Office Action, the Examiner has rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,283,959) in view of Benson (U.S. Patent No. 4,082,096) and Dobak, III (U.S. Patent No. 6,482,226).

In response to the Office Action, independent claims 1, 8 and 15 have been amended to require a cryo-fluid that is preconditioned to approximately 400psia and -40°C. Further, independent claims 1, 8 and 15 have been amended to now recite a device (claims 1 and 8) and method (claim 15) for cryoablating tissue that requires a shapeable rod-shaped element. As now claimed, this shapeable element is disposed in the cryochamber and extends substantially along and through the length of the cryochamber. In addition, independent claims 1 and 15 have been amended to specify that the shapeable rod-shaped element configures the flexible enclosure to conform to exposed tissue. To be consistent with these amendments, claims 4 and 10 have been cancelled. Claim 19 has been amended by deleting limitations now presented in amended claim 15. In addition, claim 20 has been amended to comply with the amendments to claim 15. Claims 5 and 11 have been amended to depend from a still pending claim. Support for these amendments can be found in the specification on page 4, lines 18-22, page 8, lines 7 to 22, and Fig. 3.

Amendments to the claims have been presented herein to point out the features which distinguish the present invention over the cited art. Claims 1-3, 5-9 and 11-20 remain pending.

Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 1-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,283,959) in view of Benson (U.S. Patent No. 4,082,096) and Dobak, III (U.S. Patent No. 6,482,226).

In response, independent claims 1, 8 and 15 have been amended in at least two important respects. Firstly, as indicated above, these claims now require a preconditioned cryo-fluid. Specifically, the cryo-fluid is preconditioned to enter the capillary tube (claim 1) or the flow restricting device (claims 8 and 15) at approximately 400psia and -40°C. Secondly, these claims also require a shapeable rod-shaped element extending into the cryochamber substantially along and through the length of the cryochamber. Further, claims 1 and 15 have been amended to specify that the shapeable rod-shaped element configures the flexible enclosure to conform to exposed tissue. None of the cited references, individually or in combination, teach or suggest such a structure or cooperation of structure.

With regard to the claim limitation for the present invention, to the effect that the cryo-fluid is preconditioned; none of the cited references have a preconditioning requirement for their respective fluid refrigerants/coolants. Although Lalonde et al. specifically disclose the use of liquid carbon dioxide as a coolant, and suggest the possibility of other coolants (see Lalonde et al. col. 2, lns 55-58), they do not go further to disclose a preconditioning requirement. Importantly, unlike the present invention, they have no motivation to do so. Specifically, Lalonde et al. are concerned with accomplishing

heat transfer through an inflated balloon, regardless whether the coolant is liquid or gas. The present invention, on the other hand, requires a preconditioning of its fluid refrigerant to insure there will be a liquid-to-gas transition in the cryochamber. Insofar as Dobak, III is concerned, while Dobak, III does contemplate a liquid-to-gas transition, the purpose for doing so is quite different from the present invention. Specifically, for Dobak, III, it is to perform hypothermia procedures on selected organs. The cryoablation temperatures that are essential for operation of the present invention, however, are not necessary for a hypothermia treatment. And, Dobak, III does not suggest they are. Further, the Benson reference simply does not address any requirement for preconditioning a fluid refrigerant.

With regard to a shapeable rod-shaped member that extends through the length of a cryochamber, such an element is not disclosed by any of the cited references, for the purposes now recited in the claims of the present invention. Instead of such an element, Lalonde et al. disclose an endovascular catheter with a balloon that is effectively limited to two cryochamber configurations. These are a balloon deflated configuration and a balloon inflated configuration (see Lalonde et al. col. 2, lns 43-51). It is important to note that Lalonde et al. do not teach or suggest any structure that shapes the balloon to conform it to exposed tissue. Further, with specific regard to the Dobak, III reference, reconfigurations of the device disclosed in this reference rely on changes in temperature (see Dobak, III col. 6, lns 49-54). In contrast, the shapeable rod-shaped element in the presently claimed invention is manually reconfigured to conform to the shape of the exposed tissue. Further, it is to be appreciated that the cited references, Lalonde et al.

and Dobak, III, can be further distinguished from the present invention by considering their respective applications. Specifically, the cited references disclose devices (i.e. catheters) and methods that operate within the vasculature of a patient to cryo-ablate or cool internal tissue. In contrast, all independent claims of the present invention are now directed to a device or method that operates externally to cryo-ablate exposed tissue.

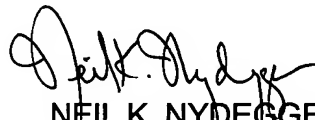
With regard to the Benson reference, Applicant respectfully contends there is no motivation for a person of ordinary skill in the art to combine Benson with either Lalonde et al. or Dobak, III to arrive at the presently claimed invention. As indicated above, the cited references are directed toward different applications. While Benson discloses methods for cryo-ablating the surface tissue of a patient, Lalonde et al. and Dobak, III, disclose devices and methods that operate within the vasculature of a patient. Accordingly, there can be significant dimensional differences between a device designed to operate within the vasculature of a person and device designed to operate external to a patient. Given this disparity in size and function, it is unlikely that the teachings in Benson would be operable with the catheters disclosed in Lalonde et al. and Dobak, III.

In light of the above arguments, Applicant respectfully contends that amended claims 1, 8 and 15 are nonobvious with respect to the cited combination of references. Further, since claims 2, 3, 5-7, 9, 11-14, 19 and 20 depend directly or indirectly from amended independent claims 1, 8 and 15, they are also nonobvious with respect to the cited combination of references. For the reasons set forth above, Applicant believes the

basis for rejecting claims under 35 U.S.C. § 103(a) has been overcome, and the rejections should, therefore, be withdrawn.

In conclusion, Applicant respectfully asserts that claims 1-3, 5-9 and 11-20 are patentable for the reasons set forth above, and that the application is now in a condition for allowance. Accordingly, an early notice of allowance is respectfully requested. The Examiner is requested to call the undersigned at 619-688-1300 for any reason that would advance the instant application to issue.

Respectfully submitted,



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